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Mazdoor Kisan Shakti Sangathan

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“पुराने को छोड़ नये के तरफ”

Jawaharlal Nehru

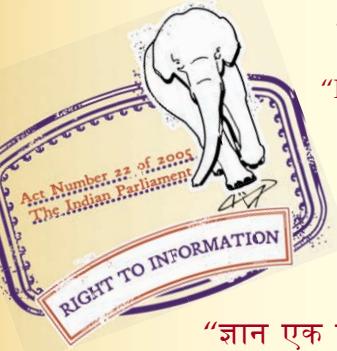
“Step Out From the Old to the New”

IS 5347-3 (1996): Requirements for orthopaedic implants,
Part 3: Unalloyed titanium [MHD 2: Orthopaedic Instruments,
Implants and Accessories]

“ज्ञान से एक नये भारत का निर्माण”

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“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartṛhari—Nītiśākām

“Knowledge is such a treasure which cannot be stolen”



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भारतीय मानक
अस्थि अन्तर्रोपणों की अपेक्षाएँ
भाग 3 असिंथ्रित टाइटेनियम
(पहला पुनरीक्षण)
Indian Standard

REQUIREMENTS FOR ORTHOPAEDIC IMPLANTS

PART 3 UNALLOYED TITANIUM

(*First Revision*)

ICS 11.040.40

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BUREAU OF INDIAN STANDARDS
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NATIONAL FOREWORD

This Indian Standard (Part 3) (First Revision) which is identical with ISO 5832-2 : 1993 'Implants for surgery — Metallic materials — Part 2 : Unalloyed titanium', issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards, on the recommendations of Orthopaedic Instruments and Accessories Sectional Committee and approval of Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1984 as dual number standard. Its first revision has been done to incorporate the modification effected in the second edition of ISO 5832-2 brought out in 1993. In this revised version chemical composition of various elements present in various grades of material has been altered with respect to iron, hydrogen and oxygen. Reference standards for test methods for mechanical properties i.e. tensile strength, proof stress and percentage elongation, etc, have been changed from ASTM to ISO.

The text of above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist.

The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 6892 : 1984	IS 1608 : 1972 Method for tensile of steel products (<i>first revision</i>)	Technically equivalent
ISO 7438 : 1985	IS 1599 : 1985 Method for bend test (<i>second revision</i>)	do
ASTM E 112 : 1988	IS 4748 : 1988 Method for estimating average grain size of metals (<i>first revision</i>)	do

This Indian Standard has been issued in twelve parts. Other parts of this Indian Standard are:

- Part 1 : General requirements
- Part 2 : Wrought stainless steel
- Part 4 : Wrought titanium 6-aluminium 4-vanadium alloy
- Part 5 : Cobalt-chromium-molybdenum casting alloy
- Part 6 : Wrought-cobalt-chromium tungsten-nickel alloy
- Part 7 : Wrought cobalt-nickel chromium-molybdenum alloy
- Part 8 : Forgeable and cold-formed-cobalt-chromium-nickel- molybdenum-iron alloy
- Part 9 : Ceramic materials based on alumina
- Part 10 : Ultra-high molecular weight polyethylene, powder form
- Part 11 : Ultra-high molecular weight polyethylene, moulded form
- Part 12 : Wrought cobalt-nickel-chromium molybdenum tungsten iron alloy.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (revised)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

REQUIREMENTS FOR ORTHOPAEDIC IMPLANTS

PART 3 UNALLOYED TITANIUM

(First Revision)

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, unalloyed titanium for use in the manufacture of surgical implants.

Provision is made for five grades of titanium based on tensile strength (see table 2).

NOTE 1 The mechanical properties of a sample obtained from a finished product made of this metal may not necessarily comply with those specified in this part of ISO 5832.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5832. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5832 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6892:1984, *Metallic materials — Tensile testing*.

ISO 7438:1985, *Metallic materials — Bend test*.

ASTM E 112:1988, *Methods for determining Average Grain Size*.

3 Chemical composition

The heat analysis when determined as specified in clause 6 shall conform to the requirements as to chemical composition prescribed in table 1. Ingot

analysis may be used for reporting all chemical requirements except hydrogen, which shall be determined after the last heat treatment and pickling procedure.

4 Microstructure

The microscopic structure of the titanium in the annealed condition shall be uniform. The grain size, determined as specified in clause 6, shall be no coarser than grain size No. 5.

5 Mechanical properties

5.1 Tensile properties

The tensile properties of the titanium, determined as specified in clause 6, shall be in accordance with the requirements of table 2.

Should any of the test pieces not meet the specified requirements, or should they break outside the gauge limits, two further test pieces representative of the same batch shall be tested in the same manner. The titanium shall be deemed to comply only if both additional test pieces meet the specified requirements.

If any of the retests fails to meet the appropriate requirements, the product represented shall be deemed not to comply with this part of ISO 5832. However, the manufacturer may, if he so desires, re-heat-treat the material and resubmit it for testing in accordance with the requirements of this part of ISO 5832.

5.2 Bending properties

Titanium alloy sheet and strip, when tested as specified in clause 6, shall not show any cracking on the outside surface of the test piece.

6 Test methods

The test methods to be used in determining compliance with the requirements of this part of ISO 5832 shall be those given in table 3.

Representative test pieces for the determination of mechanical properties shall be prepared in accordance with the provisions of ISO 6892.

Table 1 — Chemical composition

Element	Compositional limits, % (m/m)			
	Grade 1 max.	Grade 2 max.	Grade 3 max.	Grades 4A and 4B max
Nitrogen	0,03	0,03	0,05	0,05
Carbon	0,1	0,1	0,1	0,1
Hydrogen	0,012 5 ¹⁾	0,012 5 ¹⁾	0,012 5 ¹⁾	0,012 5 ¹⁾
Iron	0,15	0,2	0,25	0,3
Oxygen	0,18	0,25	0,35	0,45
Titanium	Balance	Balance	Balance	Balance

1) Except for billets, for which the maximum hydrogen content shall be 0,01 % (m/m).

Table 2 — Mechanical properties

Grade	Condition	Tensile strength ¹⁾ min. MPa	Proof stress of non-proportional elongation ¹⁾ min. MPa	Percentage elongation min.: %	Reduction of area (bars and billets only) min. %	Mandrel diameter for bend test for sheet and strip ²⁾ mm	
						where $t < 2$ mm	where $2 \text{ mm} \leq t \leq 5$ mm
1	annealed	240	170	24	30	3 t	4 t
2	annealed	345	230	20	30	4 t	5 t
3	annealed	450	300	18	30	4 t	5 t
4A	annealed	550	440	15	25	5 t	6 t
4B	cold-worked	680	520	10	18	6 t	7 t

1) Tensile, yield and bending requirements of sheet shall apply to material taken both parallel and perpendicular to the direction of rolling.

2) t = thickness of the sheet or strip

Table 3 — Test methods

Requirement	Relevant clause	Test method
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Grain size	4	ASTM E 112
Mechanical properties	5	
Tensile strength		ISO 6892
Proof stress of non-proportional elongation		ISO 6892
Percentage elongation		ISO 6892
Reduction of area		ISO 6892
Bending		ISO 7438
		Bend the sheet or strip through 105° around the mandrel of the appropriate diameter specified in table 2.

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Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Handbook' and 'Standards Monthly Additions'.

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Amendments Issued Since Publication

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